

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 115565/BAL | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
| International Application No. PCT/AU2003/001012 | International Filing Date (day/month/year) 11 August 2003 | Priority Date (day/month/year) 9 August 2002 |
| International Patent Classification (IPC) or national classification and IPC Int. Cl. 7 A61F 11/00, A61B 17/56 | | |
| Applicant COCHLEAR LIMITED et al | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

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| Date of submission of the demand 28 January 2004 | Date of completion of the report 23 November 2004 |
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929 | Authorized Officer XAVIER GISZ Telephone No. (02) 6283 2064 |

I. Basis of the report

1. With regard to the elements of the international application:*

- the international application as originally filed.
- the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
 the language of publication of the international application (under Rule 48.3(b)).
 the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority in written form.
 furnished subsequently to this Authority in computer readable form.
 The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. The amendments have resulted in the cancellation of:

- the description, pages
 the claims, Nos.
 the drawings, sheets/fig.

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

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* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|--------------------------------------|-----|
| Novelty (N) | Claims 16-19, 21, 26, 32-42 | YES |
| | Claims 1-15, 20, 22-25, 27-31 | NO |
| Inventive step (IS) | Claims 16-19, 21, 36-40, 42 | YES |
| | Claims 1-15, 20, 22-35, 41 | NO |
| Industrial applicability (IA) | Claims 1-42 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1....US 6,427,086
D2....US 6,132,384

Novelty (N) Claims 1-15, 20, 22-25, 27-31

Claims 1-10, 12-15, 20, 22-25, 27-31: D1 discloses a neurostimulator (620) implantable into a cavity in the cranium; the upper surface of the implant having a flange member (622) extending outwardly beyond the outward extent of the lower surface of the housing, the flange member adapted to abut the surface of the bone surrounding the cavity (column 35 lines 1 to 4).

Similarly D2 discloses the features of claims 1-5, 13, 14

Claim 11: D2 discloses a flange (158) which is an integral extension of the implant.

Inventive Step (IS) Claims 1-15, 20, 22-35, 41

Claims 1-15, 20, 22-25, 27-31 lack novelty and consequently lack inventive step.

Claim 26: Although D1 does not disclose the feature of making the flange integral with the faceplate, this would be considered a mere workshop improvement to a PSA and consequently lacks inventive step.

Claims 32-35: Although D1 does not disclose the feature of making the faceplate separately from the housing, this would be considered a mere workshop improvement to a PSA and consequently lacks inventive step.

Claim 41: Although D1 does not explicitly disclose all the steps of the method claimed, they would be arrived at as a matter of routine to PSA and consequently lack inventive step.